

Influence of Screw Augmentation in Posterior Dynamic and Rigid Stabilization Systems in Osteoporotic Lumbar Vertebrae

A Biomechanical Cadaveric Study

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Study Design. Biomechanical cadaveric study.

Objective. To determine whether augmentation positively influence screw stability or not.

Summary of Background Data. Implantation of pedicle screws is a common procedure in spine surgery to provide an anchorage of posterior internal fixation into vertebrae. Screw performance is highly correlated to bone quality. Therefore, polymeric cement is often injected through specifically designed perforated pedicle screws into osteoporotic bone to potentially enhance screw stability.

Methods. Caudocephalic dynamic loading was applied as quasi-physiological alternative to classical pull-out tests on 16 screws implanted in osteoporotic lumbar vertebrae and 20 screws in nonosteoporotic specimen. Load was applied using 2 different configurations simulating standard and dynamic posterior stabilization devices. Screw performance was quantified by measurement of screwhead displacement during the loading cycles. To reduce the impact of bone quality and morphology, screw performance was compared for each vertebra and averaged afterward.

Results. All screws (with or without cement) implanted in osteoporotic vertebrae showed lower performances than the ones implanted into nonosteoporotic specimen. Augmentation was negligible for screws implanted into nonosteoporotic specimen, whereas in osteoporotic vertebrae pedicle screw stability was significantly increased. For dynamic posterior stabilization system

an increase of screwhead displacement was observed in comparison with standard fixation devices in both setups.

Conclusion. Augmentation enhances screw performance in patients with poor bone stock, whereas no difference is observed for patients without osteoporosis. Furthermore, dynamic stabilization systems have the possibility to fail when implanted in osteoporotic bone.

Key words: pedicle screw, augmentation, osteoporosis, biomechanics, lumbar vertebrae.

Level of Evidence: N/A

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Osteoporosis is a more common disease in the elderly population and is continually rising. In the United States the annual cost for the management of osteoporosis was estimated at \$17 billion.¹ It is therefore becoming part of the surgical routine of spine surgeons to treat patients without osteoporosis in need of spinal decompression and instrumented fusion. Successful fusion is more likely with rigid internal fixation² and such posterior internal fixation systems undergo important internal constraints resulting in high load-bearing requirements for the pedicle screw/bone interface. Various studies have proven that the screw performance is dependent on the bone quality meaning that patients without osteoporosis may be predisposed to larger posterior internal fixation system failure rates.³⁻⁵ Screw loosening techniques, cutout experiments, and pull-out test have been performed for different bone qualities with a common outcome: Good dense quality trabecular bone enhances solid fixation, whereas osteoporotic bone increases implants failure risks.^{4,6-11} Vertebral bone stock can be augmented with cement such as polymethyl methacrylate (PMMA) or calcium phosphate cements.¹² Numerous studies investigate the pedicle screw fixation efficiency *via* pull-out test,^{7,11,13-20} although this method seems not to be the most realistic testing paradigm because resulting constraints into the system are not physiological.^{21,22} Only few studies deal with the influence of augmentation on the migration of pedicle screws under quasi-physiological

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conditions, which is a direct quantification of the posterior internal fixation system stability.^{23–26}

In this study we evaluate the effect of a pedicle screw augmentation on the screwhead motion in nonosteoporotic and osteoporotic vertebrae under quasi-physiological load by cyclic caudocephalic loading.

MATERIALS AND METHODS

Spine Preparation and Screw Implantation

The first group constituted 20 frozen cadaveric lumbar vertebrae (L1–L5) harvested on 3 females and 1 male (mean age = 70 yr, min/max 65/72 yr). The severe osteoporotic group constitutes 16 freshly frozen cadaveric lumbar vertebrae (L1–L5) collected from 4 female donors (72, 73, 78, and 79 years old). The local ethical committee approved the use of the human specimens for scientific purpose.

All vertebrae underwent preliminary radiographical studies to ensure the absence of fractures, scoliotic deformations, neoplasms, or previous spine surgery. Global bone mineral density (BMD) of the specimen was evaluated by dual energy x-ray absorptiometry measurement and was in the range between 0.671 and 0.941 g/cm² for the first group and 0.239 and 0.361 g/cm² for the second one. Vertebrae were classified into 2 groups: (1) the normal BMD group (BMD >0.6 g/cm²) and (2) the severe osteoporotic (BMD <0.4 g/cm²) one.

Prior to and in-between manipulations, the specimens were stored at –20°C. Before testing, the specimens were allowed to thaw at room temperature for 24 hours. While defrosting and during testing, the specimens were kept moist with saline solution to prevent dehydration.

A spine surgeon conducted the preparation. Periosteum, longitudinal ligaments, and half of the discs were left intact. The pedicles were prepared using a pedicle awl to open the dorsal cortex and a pedicle probe (both from Synthes Inc., Solothurn, Switzerland) to create the cavity inside the pedicle. The correct position of the probe was controlled by image intensifier (Siremobil; Siemens Medical Solutions, Zurich, Switzerland). Dual-core perforated Click'X pedicle screws (Synthes Inc., Solothurn, Switzerland) of 50-mm length were inserted in each pedicle of the vertebrae. A controlled volume of PMMA (2 mL of Spine Fix Cement; Technimed SA, Bigorre, France) was injected on one side yielding an augmented and nonaugmented screw fixation contralaterally. No cement extravasation was found in the specimen. All specimens were checked under the C-arm, in all cases a cloud of PMMA was found around of the screw.

Mechanical Tests

All implanted pedicle screws were subject to caudocephalic compression forces applied with a servohydraulic testing device (Zwick 1475; Zwick Roell Group, Ulm, Germany) to the head of the screws. As depicted in Figure 1, 2 alternative connections between the rod and the screwhead were used as explained in the text hereafter:

- (1) The machine's rod was pushing on the screw by a piston allowing free movement in-between the head of the

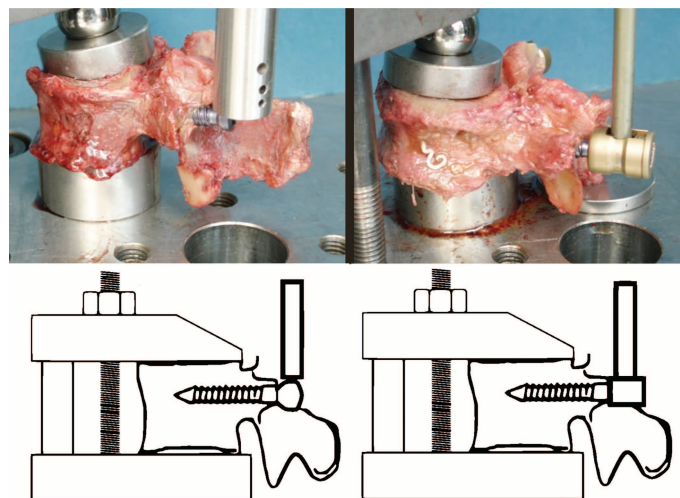


Figure 1. Testing setup showing the vertebrae fasten between both cylinders. The left picture corresponds to the free connection similar to posterior dynamic stabilization system, whereas the right picture is related to the blocked connection (standard posterior stabilization system).

screw and the rod (free connection [FC]¹³). This connection simulates dynamic fixation devices in which motions between the pedicle screws and dorsal stabilizers are possible;

- (2) The machine's rod and the screw were connected by the blocked universal joint *via* a fixed angle, not allowing any motion between the head of the screw and the rod (blocked connection [BC]^{23,24}). This is simulating an angular stable dorsal instrumentation device.

The vertebrae were fastened on their endplate between 2 metallic cylinders, which were grounded on the compression device table.

The load scenario was composed of 3 consecutive load steps having 50 sinusoidal cycles each. The first level was ranging between 5 and 50 N, the second between 5 and 100 N, and the third between 5 and 200 N. The testing device induced a force on the screw *via* a constant displacement of its rod (20 mm/min) until the end force of each cycle was reached (50 N, 100 N, and finally 200 N). Displacements in load application direction were recorded by the servohydraulic testing device sensors.

Data Processing

All statistical analyses were conducted using SAS version 9.1 (SAS Institute Inc., Cary, NC). The outcomes of the compression test were plotted (load in function of displacement) to observe the global behavior of the load/displacement relationship.

A load level was regarded as “successful” when no relative displacement could be observed at the end of the load level (displacement of the screwhead occurring between 2 cycles), otherwise it was regarded as “failed.” For each successful load level the global displacement was evaluated. This value corresponds to the screwhead displacement between the first and the last cycle of each load level.

Because anatomical differences in the geometrical and mechanical characteristics of each of the vertebra are different, there is a certain variability in the screw implantation direction. Studies have proven the importance of this factor on screw fixation efficiency.^{27–29} To reduce possible variability “relative global displacement” was implemented: global displacements were compared contralaterally for each vertebra by the means of the migration ratio. The migration ratio corresponds to the global displacement of the augmented screws compared with the nonaugmented screws. A migration ratio smaller than one indicates that augmented screws have less global displacement than the nonaugmented ones. Migration ratios of each group (BC augmented, BC nonaugmented, FC augmented, and FC nonaugmented) were compared with a uniform distribution of 1 *via* the Student *t* test (unilateral and inhomogeneous test assumed significant for $P < 0.05$) to obtain a statistical outcome.

RESULTS

Compression Test

The screwhead-load displacement showed 3 types of displacement: (1) irreversible displacement, which can be related to migration (Figure 2), (2) reversible displacement linked to micromotions³⁰ (Figure 2), and (3) divergent displacement corresponding to screw failure (Figure 3).

Nonosteoporotic Group

A comparison of the migration of augmented and nonaugmented specimens revealed no difference (Figures 4, 5, A = free connection, B = blocked connection). Furthermore, both test setups showed similar results even if FC tended to have higher values (total average maximum migration of 0.3 ± 0.2 mm). Applying the migration ratio did not show notable differences between the mentioned groups (Figure 6).

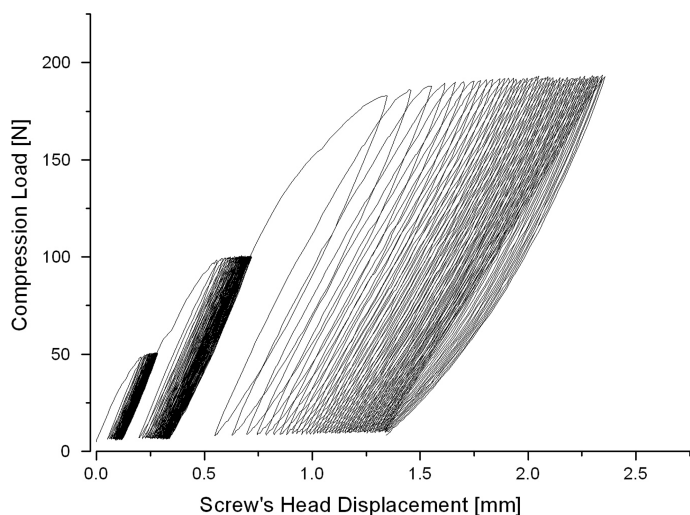


Figure 2. Typical load-displacement pattern of pedicle screws undergoing successfully cyclic caudocephalad loading: convergence is observed for all load steps.

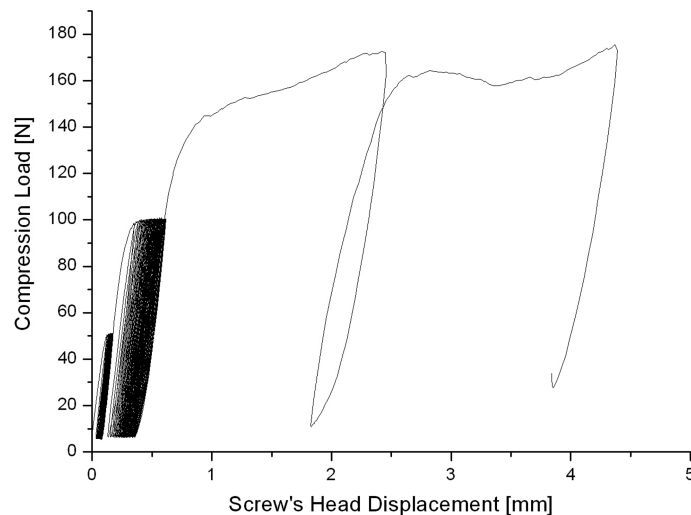


Figure 3. Typical load-displacement pattern of pedicle screws failing 200-N cyclic caudocephalad loading: after convergence of the 50-N and 100-N load steps.

Osteoporotic Group

Two different screwhead-displacement patterns were observed for the full load scenario (all 3 load levels): (1) for the BC setup all 3 loads were successful (Figure 2), (2) whereas, the FC setup exhibits only 2 successful load levels (50 N and

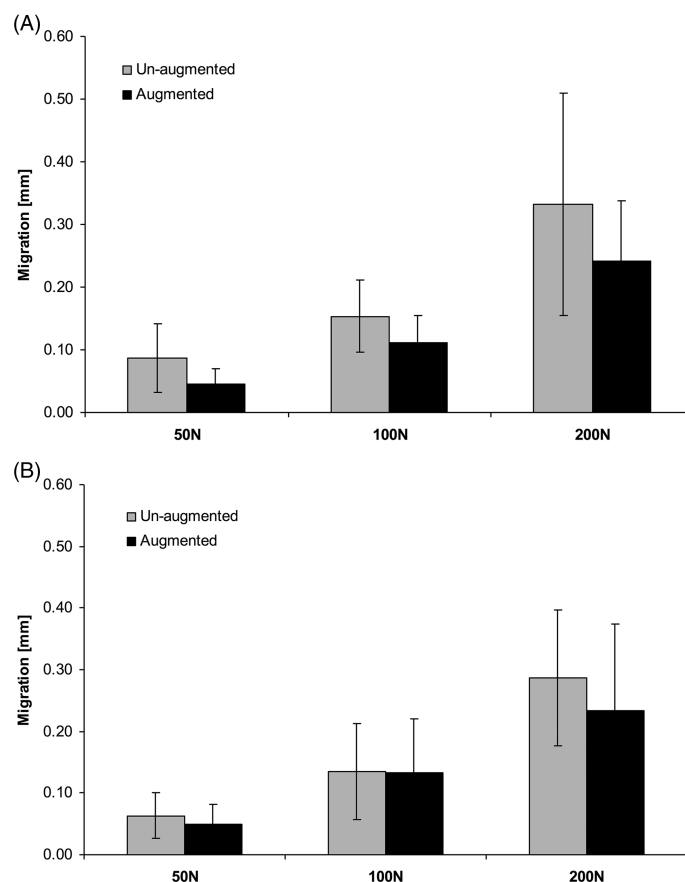


Figure 4. Averaged pedicle screwhead migration at the end of each load step for nonosteoporotic vertebrae. **A**, Results of FC tests. **B**, Results of BC investigations.

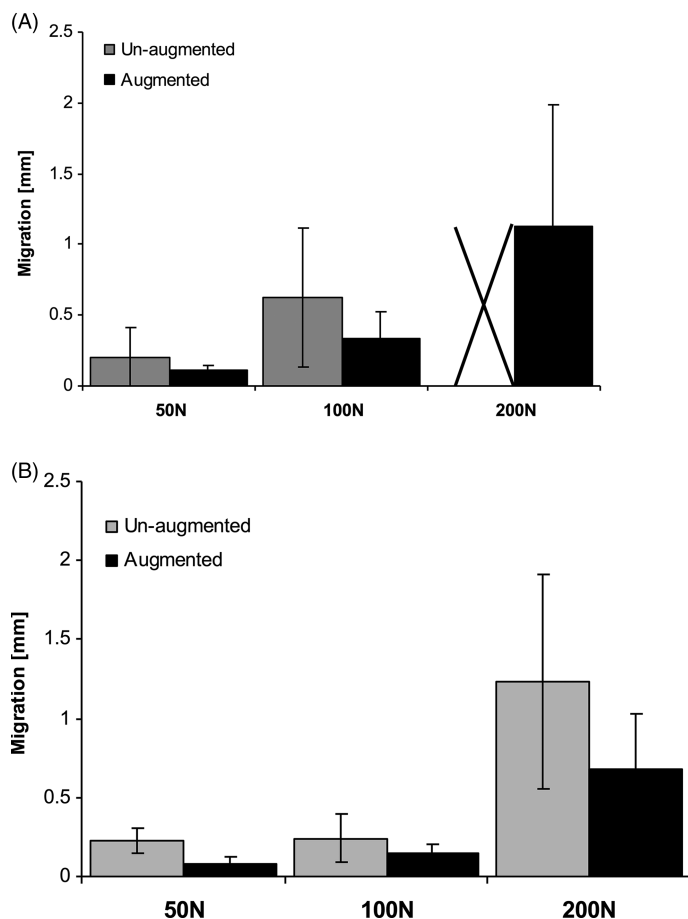


Figure 5. Averaged pedicle screwhead migration at the end of each load step for severe osteoporotic vertebrae. **A**, Results of FC tests (the cross is related to systematic implant failure). **B**, Results of BC investigations. FC indicates free connection; BC, blocked connection.

100 N) (Figure 3), because the 200-N load level systematically failed.

In Figure 4, the averaged migration and its standard deviation is represented for each group. Comparison between augmented and nonaugmented screws revealed no differences ($P > 0.4$). By examining both testing methods (FC and BC), FC tends to induce a larger migration of the screwhead without statistical significance. Migration larger than 1 mm was observed for the 200-N load cases accompanied by important standard deviations.

The migration ratio of the last successful load level ($P = 0.039$ for 200 N) was significantly smaller than the one for the BC test ($P = 0.007$ 100 N for the FC, respectively) meaning that augmented screws migrate less (Figure 7).

DISCUSSION

Implant failure is an increasing problem in osteoporotic bone. To judge if additional augmentation is needed, bone strength can be determined either preoperatively by measurement of BMD or intraoperatively by using mechanical peak torque measurement tools.^{31,32} To investigate efficiency of augmentation *via* perforated pedicle screws, we used an alternative testing model to standard pull-out test.^{33–35} Therefore, cyclic

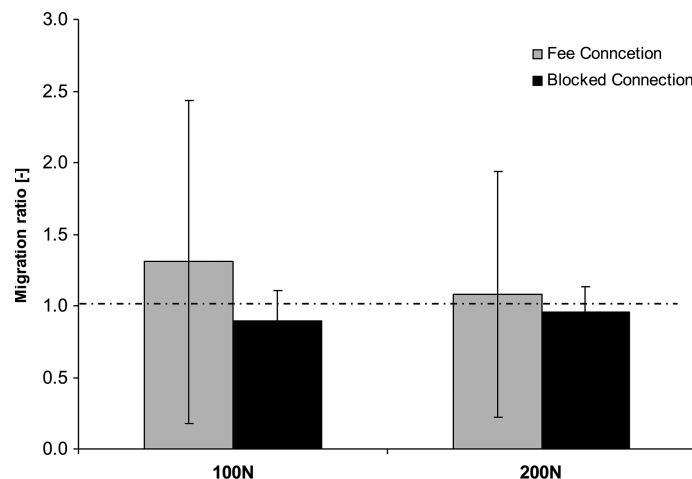


Figure 6. Migration ratio for nonosteoporotic specimens. To enhance the readability, a line at value 1 has been drawn, which corresponds to the migration ratio value where both augmented and nonaugmented pedicle screw migrations are equal. FC indicates free connection; BC, blocked connection.

caudocephalic compression was performed on perforated pedicle screws implanted into 16 severely osteoporotic vertebrae and 20 nonosteoporotic specimens.

To simulate dynamic and angular stable posterior stabilization, 2 different connection methods between the loading device and the screwhead were used.

As expected, screwhead migration in osteoporotic vertebrae was larger than in nonosteoporotic specimens (3-fold, 2.5-fold was reported for screws undergoing pull-out test.³⁵). Focusing on the last successful load step, an analyzing method reducing interspecimen heterogeneity has revealed a significant positive influence of augmentation on screwhead migration for all screws implanted into osteoporotic vertebrae. However, no significant differences were observed in non-osteoporotic specimens.

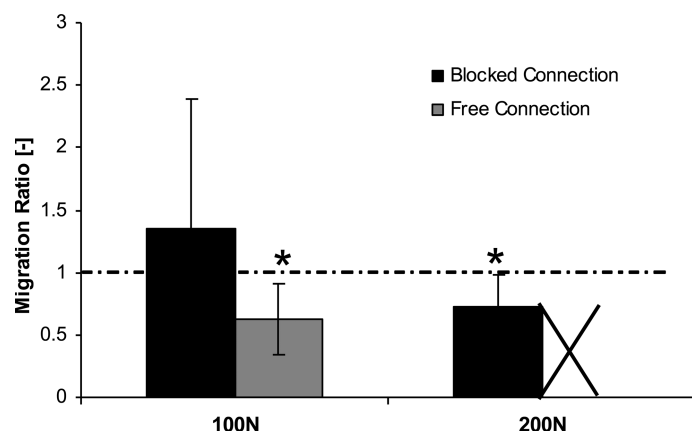


Figure 7. Migration ratio for osteoporotic specimens. To enhance the readability, a line at value 1 has been drawn, which corresponds to the migration ratio value where both augmented and nonaugmented pedicle screw migrations are equal. The star shows the migration that are statistically smaller than 1 ($P < 0.05$). The cross is related to systematic implant failure.

In osteoporotic vertebrae, the effect of augmentation was significant but migration remains larger than that for normal bone quality specimens. The authors hypothesize that augmentation reduces the pedicle screw migration by increasing the load transmission surface and creating an interlocking between the cement and the cancellous bone reducing screw-head micromotion and migration. The good bone quality of nonosteoporotic vertebrae seems to be sufficient to withstand the loading applied in this study. Turner *et al*²⁴ had already addressed this issue. They implemented similar reinforcement mechanisms using different testing condition and specimens (only normal BMD vertebrae were investigated), and concluded that augmenting the bone/cement interface increases bone strength and reduces the stress level.¹²

In our study, the sum of migration and micromotion averages values of 1 mm for the last load case (200 N) in the osteoporotic group, whereas nonosteoporotic specimens showed migrations close to 0.5 mm. These values are smaller than the already published data but in a similar range (~ 1 mm for PMMA augmented screws^{23,24} for nonosteoporotic vertebrae). We explain these differences due to the different setups: Tan *et al*²³ applied a 300-N compression force and a 5-Nm torque on the screw for 100 cycles; whereas Turner *et al*²⁴ used a displacement-controlled load application for 1600 cycles (load scenario effects are discussed thereafter). According to the literature, compressive forces reaching up to 300 N occur in spinal fixation device during walking.^{36–38} In our study, the maximum load was set to 200 N because of the high failure rate observed in the FC configuration and in severe osteoporotic specimens when applying higher loads. Furthermore, the 200-N choice is reinforced by the significant differences observed between both groups. The authors expect larger load to magnify the differences measured in this study.

A limitation of the proposed load scenario is to be found in the absence of traction and compression forces as observed *in vivo*.^{36,37,39,40} Compression forces seem to cause more damage to the vertebrae because their intensities are 10 times larger.²³ When comparing the number of cycles (only 3×50 cycles) with other publications (from 100 to 1600 cycles^{23,24,41}), one could argue the results obtained with such short loading periods. However, once a load level converged, only micromotions occurred showing that the system has reached equilibrium and further loading with equal intensity should not affect the tested specimens. In the collected data, the 2 scenarios observed were convergence and divergence meaning that no further migrations occurred (convergence) or that the implant failed (divergence), hence the limitation to 3×50 cycles were justified.

In our study, 2 kinds of connections were used: the free one and the fixed one. Transferred to clinic the FC simulates dynamic fixations, whereas the BC simulates angle stable posterior stabilization techniques. It is true that in a clinical situation the force transmission is different due to the “dynamic” connection of the screws, nevertheless we think our model to be more physiological compared with standard pull-out tests. In our study, the difference between the BC and the FC is obvious for the osteoporotic specimens: migration is higher

for the FC and only screws tested in the FC configuration failed. These results were expected because the BC induces a torque into the screw, reducing the energy available to deform the vertebra.

Cement distribution around the screw is a critical point in the literature. For data processing, it was assumed that cement distribution was similar for every specimen. In all cases a cement cloud was found around the tip of the screws.

CONCLUSION

The proposed study shows that under quasi-physiological caudocephalic loading, augmentation positive influences screw anchorage in vertebrae with low BMD. We conclude that patients with good bone quality (in this experimental setup, BMD of >0.8 g/cm²) do not require pedicle screw augmentation, whereas in severe osteoporotic bone (BMD <0.3 g/cm²) augmentation results in a relevant diminution of screwhead migration. Using the FC between the testing device rod and the screw leads to early implant failure osteoporotic specimen. This should be taken into consideration when applying dynamic stabilization systems in osteoporotic bone.

➤ Key Points

- ❑ Augmentation increases pedicle screw performances for osteoporotic vertebrae.
- ❑ Augmentation has no influence on screw performance in nonosteoporotic bone.
- ❑ Dynamic stabilization systems have the possibility to fail in patients without osteoporosis.

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